UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,064	07/18/2003	Martin F. Bachmann	1700.0300001/BJD/SJE	5977

26111 7590 09/17/2004

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,064	BACHMANN ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-115* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-68, drawn to conjugate and compositions thereof, classified in class 530, subclass 403. If this group is elected, election of species is further required.

II. Claims 69-74, drawn to method of inducing an immune response to a drug, classified in class 424, subclass 193.1. If this group is elected, election of species is further required.

III. Claims 75-78, 86, drawn to antibody that recognizes a hapten, classified in class 530, subclass 388.9. If this group is elected, election of species is further required.

IV. Claims 79-80, drawn to assay method using antibody, classified in class 436, subclass 501. If this group is elected, election of species is further required.

V. Claims 81-85, drawn to body treating methods using antibody, classified in class 424, subclass 175.1. If this group is elected, election of species is further required.

VI. Claims 87-89, 92-115, drawn to body-treating method using conjugate and composition combinations used in method, classified in class 424, subclass 193.1.

Claims 90-91 are not included in any group as these are nonstatutory "use" claims which are so vague as to render it impossible to determine which invention they should be grouped with.

The inventions are distinct, each from the other because of the following reasons:

Groups I and III are drawn to patentably distinct products, an antigenic conjugate and an antibody, respectively. Althought the antibody is claimed in product-by-process terms reciting use of the conjugate in the process of inducing the antibody, the products are nonetheless distinct because an identical antibody could be made by a materially different process, such as a process using a hapten conjugated to keyhole lymphocyte hemocyanin (KHL).

Group I is related to groups II and VI related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, as broadly claimed, can be used in a materially different method, such as a process of inducing an immune response against a non-drug hapten, such as a hormone or toxin.

Group I is unrelated to groups IV and V, since the processes in groups VI and V use a different product.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made materially different process, such as a process using a hapten conjugated to keyhole lymphocyte hemocyanin (KHL).

Groups II, IV, and V are unrelated, being processes that use different materials and/or different active steps to achieve different results.

Inventions II and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination for patentability because the method of treating or preventing addition (the combination) necessarily involves a subject which is addicted or likely to become addicted, whereas the method of inducing an immune response (the subcombination) merely involves a subject capable of producing antibodies. In other words, patentability in invention VI relies at least in part upon patient choice, which is not one of the particulars of the subcombination of invention II.

Invention II is related to inventions IV and V as product and alternative materially different processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody, as claimed, can be used in the immunoassay method of group IV or the therapeutic method of group V.

Group III is unrelated to group VI because the process of group IV does not use the product of group III.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

Groups I-V contain claims generic to a plurality of disclosed patentably distinct species of hapten or hapten-reactive materials, see list of haptens below. Group I also contains claims generic to a plurality of disclosed carriers, see list of carriers below. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of hapten (for groups I-V) and a single disclosed species of carrier (for group I), even though this requirement is traversed.

Hapten species:

codeine

fentanyl

heroin

morphine

amphetamine

cocaine

methylenedioxymethamphetamine

methamphetamine

methylphenidate

nicotine

cotinine

nornicotine

PCP

LSD

mescaline

psilocybin

tetrahydrocannabinol

diazepam

desipramine

imipramine

nortriptyline

amitriptyline class

Progesterone

Estrogen

Testosterone

follicle stimulating hormone

melanin stimulating hormone

adrenalin

noradrenalin

Aflatoxin

ciguatera toxin

tetrodotoxin

antibiotic

anticancer agent

Carrier species:

Virus

Hepatitis B VLP

rneasles VLP

sindbis VLP

rotavirus VLP

Foot-and-Mouth-Disease VLP

Retrovirus VLP

Norwalk VLP

Alphavirus VLP

Human Papilloma VLP

Polyoma VLP

Bacteriophage VLP

Ty VLP

QB-phage or VLP

GA-phage or VLP

Fr-phage or VLP

AP205 phage or VLP

bacteriophage R17

bacteriophage SP

bacteriophage MS2

bacteriophage M11

bacteriophage MX1

bacteriophage NL95

bacteriophage F2

bacteriophage PP7

The species of hapten are seen as patentably distinct from each other because each involves a structurally distinct molecule with a distinct biological activity. The species of carrier are seen as patentably distinct because because none of the species share common structure with the other species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600

9/10/04